Pursuant to the authority vested in the Public Health and Health Planning Council and Commissioner of Health by section 2803 of the Public Health Law, sections 405.7 and 751.9 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register:

Paragraph (10) of subdivision (c) of section 405.7 of Title 10 is amended to read as follows:

(10) Receive all the information you need to give informed consent for an order not to resuscitate. You also have the right to designate an individual to give this consent for you if you are too ill to do so. If you would like additional information, please ask for a copy of the pamphlet "[Do Not Resuscitate Orders] <u>Deciding About Health Care</u> - A Guide for Patients and Families."

Subdivision (1) of section 751.9 is amended to read as follows:

(l) express complaints about the care and services provided and to have the center investigate such complaints. The center is responsible for providing the patient or his/her designee with a written response within 30 days if requested by the patient indicating the findings of the investigation. The center is also responsible for notifying the patient or his/her designee that if the patient is not satisfied by the center response, the patient may complain to the New York State Department of [Health's Office of Health Systems Management] Health;

Subdivisions (p) and (q) of section 751.9 are amended, and new subdivisions (r) and (s) are added to read as follows:

- (p) authorize those family members and other adults who will be given priority to visit consistent with your ability to receive visitors; [and]
- (q) when applicable, make known your wishes in regard to anatomical gifts. Persons sixteen years of age or older may document their consent to donate their organs, eyes and/or tissues, upon their death, by enrolling in the NYS Donate Life Registry or by documenting their authorization for organ and/or tissue donation in writing in a number of ways (such as health care proxy, will, donor card, or other signed paper). The health care proxy is available from the center[.];
- (r) view a list of the health plans and the hospitals that the center participates with; and (s) receive an estimate of the amount that you will be billed after services are rendered.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 2803 authorizes the Public Health and Health Planning

Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the

Commissioner of Health (Commissioner), to implement the purposes and provisions of PHL

Article 28 and to establish minimum standards governing the operation of health care facilities.

PHL § 24 requires diagnostic and treatment centers (D&TCs) to disclose the health care plans in which they are participating providers and the hospitals with which they are affiliated; and it also requires D&TCs to make available estimates of the amounts patients will be billed.

Legislative Objectives:

The legislative objectives of PHL Article 28 include the protection of the health of the residents of the State by promoting the efficient provision and proper utilization of high quality health services at a reasonable cost.

PHL § 24 is intended to protect D&TC patients against unknowingly receiving care from out-of-network providers, resulting in surprise medical bills.

Needs and Benefits:

Under PHL §24, D&TC patients have the right to receive information regarding the health plans and the hospitals that the center participates with and an estimate of the amount that the patient will be billed after services are rendered. The purpose of this disclosure is to ensure that patients have the information that they need to make decisions about their healthcare and to protect themselves against receiving unexpected bills. This proposed regulation revises the

D&TC Patients' Bill of Rights to inform patients of their rights under PHL §24 by adding new subdivisions (r) and (s) to 10 NYCRR §751.9. The proposed regulation mirrors similar provisions in the Patients' Bill of Rights applicable to general hospitals under 10 NYCRR 405.7.

The proposed amendment to Section 405.7 reflects a change to the Department publication that patients can request to provide them with additional information regarding medical decision-making, resuscitation, health care proxies and other end-of-life decision-making. This information was updated to implement the Family Health Care Decisions Act, effective in 2010. This regulation amendment will bring the regulations into conformance with the current Department publications.

The amendment to Section 751.9(l) deletes a reference to a Department office that has been renamed.

COSTS:

Costs to Private Regulated Parties:

This amendment is a clarification of rights that patients already have in New York State.

D&TCs will incur minimal costs to change the Patients' Bill of Rights made available to patients. D&TCs may also need to update training materials for staff.

Costs to Local Government:

This proposal will not impact local governments unless they operate a general hospital or D&TC, in which case the impact would be the same as outlined above for private parties.

Costs to the Department of Health:

The proposed regulatory changes will not result in any additional operational costs to the Department of Health, other than to provide for translations of the newly updated Bills of Rights.

Costs to Other State Agencies:

The proposed regulatory changes will not result in any additional costs to other state agencies.

Local Government Mandate:

The proposed regulations do not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

Paperwork:

D&TCs are already required to make the Patients' Bill of Rights available to patients.

Therefore, the proposed regulations should not increase their paperwork.

Duplication:

There are no relevant State regulations which duplicate, overlap or conflict with the proposed regulations.

Alternatives:

The alternative would be to take no action, which would result in a lack of consistency

between PHL §24 and the Patients' Bill of Rights.

Federal Standards:

The proposed regulations do not duplicate or conflict with any federal regulations.

Compliance Schedule:

The regulations will be effective upon publication of a Notice of Adoption in the New

York State Register.

Contact Person: Katherine Ceroalo

New York State Department of Health

Bureau of Program Counsel, Regulatory Affairs Unit

Corning Tower Building, Room 2438

Empire State Plaza

Albany, New York 12237

(518) 473-7488

(518) 473-2019 (FAX)

REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed regulation will apply to all diagnostic and treatment centers (D&TCs) in New York State. This proposal will not impact local governments or small business unless they operate a general hospital or D&TC. In such case, the flexibility afforded by the regulations is expected to minimize any costs of compliance as described below.

Compliance Requirements:

These regulations will require D&TCs to change their Patients' Bill of Rights.

Professional Services:

This proposal will not require any additional use of professional services.

Compliance Costs:

Compliance costs are minimal, as they only require editing and reprinting the Patients' Bill of Rights.

Economic and Technological Feasibility:

This proposal is economically and technically feasible.

Minimizing Adverse Impact:

The anticipated impact of the proposal is minimal. D&TCs are already required to make

the Patients' Bill of Rights available to patients.

Small Business and Local Government Participation:

Organizations that include D&TCs as members were consulted on the proposed regulations. Additionally, the proposed regulation will have a 60-day public comment period.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a "cure period" or other opportunity for ameliorative action to prevent the imposition of penalties on a party subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one is not included. As this proposed regulation does not create a new penalty or sanction, no cure period is necessary.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (http://quickfacts.census.gov).

Approximately 17% of small health care facilities are located in rural areas.

.Allegany County	.Greene County	.Schoharie County
.Cattaraugus County	.Hamilton County	.Schuyler County
.Cayuga County	.Herkimer County	.Seneca County
.Chautauqua County	.Jefferson County	.St. Lawrence County
.Chemung County	.Lewis County	.Steuben County
.Chenango County	.Livingston County	.Sullivan County
.Clinton County	.Madison County	.Tioga County
.Columbia County	.Montgomery County	.Tompkins County
.Cortland County	.Ontario County	.Ulster County
.Delaware County	.Orleans County	.Warren County
.Essex County	.Oswego County	.Washington County
.Franklin County	.Otsego County	.Wayne County
.Fulton County	.Putnam County	.Wyoming County
.Genesee County	.Rensselaer County	.Yates County
·	.Schenectady County	•

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

.Albany County	.Monroe County	.Orange County
.Broome County	.Niagara County	.Saratoga County
.Dutchess County	.Oneida County	.Suffolk County
.Erie County	.Onondaga County	·

There are approximately 90 diagnostic and treatment centers (D&TCs) in rural areas.

Reporting, Recordkeeping, Other Compliance Requirements and Professional Services:

The proposed regulation is applicable to those D&TCs located in rural areas and is expected to impose minimal costs, because regulated facilities are already required to make the Patients' Bill of Rights available to patients. Because the proposed regulatory requirements can be incorporated into existing processes, they are not expected to increase the administrative burden on these entities.

Costs:

D&TCs are already required to post the Patients' Bill of Rights in areas that are highly visible to patients. The cost of the small wording change to the Patients' Bill of Rights will be insubstantial.

Minimizing Adverse Impact:

The impact is minimal.

Rural Area Participation:

Organizations that include as members general hospitals and D&TCs located in rural areas were consulted on the proposed regulations.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.